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(54) **Specimen collection assembly with cap**

(57) The present invention is a collection assembly (10) comprising a container (12), a cap assembly (14) removably and sealably secured to the container (12) whereby access to the interior of the container (12) can be made with a piercing element without removing the cap assembly (14) from the container. The cap assembly includes a cap body (30) and a membrane like septum (32) supported by the cap body (30). The septum (32) provides for a pierceable element to have access to the interior of the container. The membrane is a thermoplastic elastomer and is self-sealing upon removal of the piercing element.

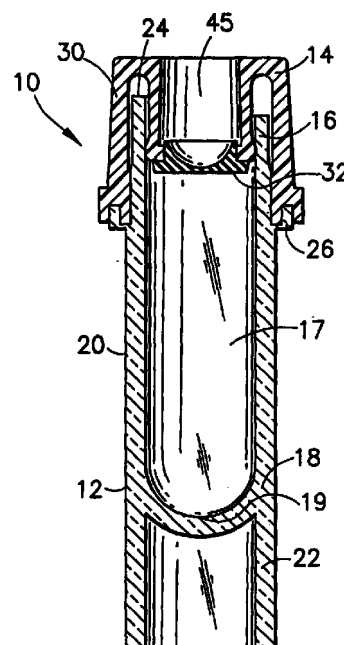


FIG.3

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Description

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0001] The present invention relates to a collection assembly and more particularly to a microcollection container and cap assembly suitable for collecting small quantities of a specimen such as blood from a patient, that provides access to the interior of the container without the need for removing the cap from the assembly and for maintaining a specimen in secure fashion for subsequent testing.

2. Description of Related Art

[0002] Analytical instrumentation has made it possible to carry out a variety of hemological diagnostic procedures on very small quantities of blood. The blood may be collected from a small puncture placed in a patient's finger or ear lobe. The blood is collected in a microcollection container. Once the small quantities of blood are collected, the container is sealably covered by a cap.

[0003] In order for a laboratory technician to conduct tests on the blood sample which is collected in the container, the cap must be removed from the container so as to provide access to the blood sample. In the alternative, the entire contents of the container may be transferred from the container to an instrument compatible sample holder in order for laboratory analysis to take place.

[0004] Therefore, there is a need for a microcollection container that is (i) compatible with instruments for laboratory analysis whereby the specimen does not have to be transferred out of the container for analysis to be conducted; (ii) provides a resealable portion for easy access into the container by a needle or probe that also prevents specimen leakage out of the container; (iii) maintains a specimen in secure fashion; and (iv) prevents contamination to the specimen and to the user.

SUMMARY OF THE INVENTION

[0005] The present invention is a collection assembly comprising a container and a cap.

[0006] The container includes an open end, a closed end and a cylindrical wall therebetween which preferably comprises the interior of the container for accommodating the specimen.

[0007] Desirably, the cap comprises a cap body removably sealably secured to the open end of the container. The cap body supports a membrane for providing resealable access to the interior of the container. The membrane is formed of a material which is capable of being pierced and resealed on a repetitive basis with a needle or instrument probe. Most preferably, the mem-

brane is formed of a thermoplastic elastomer. Such thermoplastic elastomers include isoprene propylene, such as MONOPRENE (a trademark of QST, Inc.) sold by QST, Inc., St. Albans, Vermont.

[0008] Preferably, the membrane is disc-shaped having a concave surface facing away from the container interior which assists in resealing of the membrane. The thermoplastic elastomer allows for the resealing of the pierced membrane in a manner which prevents specimen leakage therethrough even when the collection assembly is held in an inverted position.

[0009] Preferably, the cap body includes a top portion, a bottom portion, a cylindrical sidewall extending from the top portion to the bottom portion having an inner surface and an outer surface, an access passageway at the top portion and a membrane supported across the passageway.

[0010] The cap body may further include a depending annular skirt extending into the interior of the container from the top portion and defining an annular region with the cylindrical sidewall. The open end of the container is accommodated within the annular region. The depending skirt includes an access passageway, with the membrane being supported across the passageway.

[0011] Preferably, the membrane and the cap body may be co-injection molded or insert molded.

[0012] An advantage of the present invention is that it facilitates direct access to a sample for diagnostic instrumentation systems and enables microcollection tube compatibility with diagnostic instrumentation by providing features such as pierceability and self-resealing of the cap.

[0013] Still another advantage of the present invention is that the self-sealing pierceable cap permits mixing of the specimen in the container without transferring the specimen to another container and providing for direct access to the specimen via the self-sealing pierceable cap by diagnostic instrumentation.

[0014] Most notably, is that the present invention permits a specimen to be accessed through the top of the cap without removing the cap from the container, thereby providing minimal exposure of the specimen to the user.

[0015] In addition, the present invention permits the assembly to be directly used on instrumentation similar to that used for evacuated collection assemblies.

[0016] Advantages of the membrane of the present invention include that: (i) it can be pierced and resealed many times; (ii) it requires less than 2 lb. force for a piercing element to pierce it; and (iii) the concave shape aids in the ability of the membrane to seal properly after the piercing element is removed.

DESCRIPTION OF THE DRAWINGS

[0017]

FIG. 1 is a front plan view of the collection assembly of the present invention.

FIG. 2 is a perspective view of the collection assembly of FIG. 1 illustrating the container, the cap and the membrane.

FIG. 3 is a cross sectional view of the collection assembly of FIG. 1.

FIG. 4 is a side elevational view, partially in section of the collection assembly of FIG. 3.

FIG. 5 illustrates the collection assembly of FIG. 4, with a probe extending thereinto.

DETAILED DESCRIPTION

[0018] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1-3 illustrate the collection assembly **10** of the present invention.

[0019] Collection assembly **10** includes a container **12** and a cap assembly **14**. Cap assembly **14** may be removably secured to the container.

[0020] Container **12** is an elongate member having an open upper end **16**, a lower end **18** including a rounded closed bottom **19** and a cylindrical wall **20** extending therebetween. The cylindrical wall **20** defines an interior **17** internally thereof for accommodating a specimen such as a blood specimen. The cylindrical wall **20** extends beyond the rounded closed bottom **19** to form an annular extension **22** which permits container **12** to stand upright on a flat surface.

[0021] As shown in FIG. 2, open upper end **16** of container **12** includes a beveled distal rim **24** for facilitating collection of a blood sample. The upper end **16** of tube **12** further includes a radially outwardly extending cap seating flange **26** which provides for the removable sealable attachment of cap assembly **14** on upper end **16** of container **12**. Once a specimen, such as blood is collected in interior **17** of the container, the container may be sealingly closed by cap assembly **14**.

[0022] Referring to FIG. 4, cap assembly **14** includes a cap body **30** and a sealable septum **32** supported by cap body **30**. Cap body **30** is preferably an integrally formed molded plastic member generally in the shape of an inverted cup. The cap includes a flat upper surface **34**, an opposed open lower surface **36** and a cylindrical sidewall **38** extending therebetween. The distal end of cylindrical sidewall **38** adjacent open lower surface **36** defines an annular groove **39** for accommodating cap seating flange **26** of the container. Cylindrical side wall **38** includes a plurality of inwardly

directed protrusions **40** which engage an exterior surface of cylindrical wall **20** of the container about open upper end **16** to provide sealed engagement between cap body **30** and container **12**.

[0023] Cap body **30** further includes a centrally located depending annular skirt **42** extending from flat upper surface **34**. Annular skirt **42** and cylindrical side wall **38** form an open ended annular recess **43** therebetween for accommodating upper end **16** of container **12**.

Annular skirt **42** includes an open upper extent **44**, an opposed open lower extent **46** extending into interior **17** of the container and a central passageway **45** therebetween which provides access through cap body **30** and into interior **17** of container **12**. Lower extent **46** of annular skirt **42** includes an outwardly directed annular rib **48** which is engageable with an inner surface of cylindrical wall **20** adjacent open upper end **16** of container **12** to facilitate sealing of cap body **30** with container **12**.

[0024] Cap body **30** further supports septum **32** at the lower extent **46** of annular skirt **42**. Septum **32** is a disc-like membrane formed of a thermoplastic elastomer. As shown in FIG. 4, septum **32** includes a planar portion **50** and an upwardly extending annular ridge **52**. Annular ridge **52** has a diameter which allows it to be force fitted within open lower extent **46** of annular skirt **42** and retained in sealed engagement. Planar portion **50** of septum **32** faces towards the interior of container **12**. Annular ridge **52** defines a concave surface **53** in opposition to planar portion **50**. Septum **32** defines a centrally located portion **54** having a thickness of about .028 inches. Portion **54** allows the septum to be easily pierced by a cannula or probe used to extract a liquid sample from interior **17** of container **12** with about 2 pounds of force.

[0025] In use, a liquid sample is collected in container **12** and then cap assembly **14** is sealably secured to the open upper end of the container.

[0026] As shown in FIG 5, a sample probe or cannula **60** may be inserted into container **12** by inserting cannula **60** through passageway **45** of cap body **30**. The distal tip **62** of cannula **60** may then pierce through septum **32** at portion **54**. Since the material of septum **32** is a soft thermoplastic elastomer, septum **32** is easily pierced by low insertion forces. Therefore, for a relatively wide instrument probe having a diameter of about .0625 inches, portion **54** of septum **32** may be pierced by a force of less than 2 pounds.

[0027] Insertion of cannula **60** continues until it reaches the sample in interior **17** of container **12** and then collects a portion of the sample. Cannula **60** is then removed by withdrawing it back through passageway **45**. Upon withdrawing cannula **60** from septum **32**, the thermoplastic elastomer septum self-seals. In addition, concave surface **50** facing in opposition thereto helps reseal a hole placed in septum **32** by cannula **60**. The septum shape defines a concave surface in the direction of cannula withdrawal. The compressive forces exerted by such a shape assist in resealing of any hole

placed in septum **32** as cannula **60** is withdrawn from the container. Thus, the particular configuration of septum **32** as well as the material from which it is formed permits the septum to reseal after multiple puncture sites have been placed therein. The liquid sample in container **12** can therefore be repeatedly sampled with the septum self-sealing upon each sample extraction.

[0028] The collection assembly of the invention may be made of a molded thermoplastic material so that the specimen collected may be readily viewed. Representative materials include, for example, polyethylene, polypropylene and polyvinyl chloride. The collection container may incorporate a hydrophilic material or a silicon, or a texture may be applied to the internal surface thereof for enhancing the flow and mixing of blood introduced into the container.

[0029] Although it is within the purview of the invention to provide caps which are colored to defined specific forms of fluid collection containers containing materials for one reason or another or for defining the kind of examination to be conducted on the specimen collected, transparent caps may be provided. Also, it should be noted that the dimensions of the container are such as to provide space for labeling which may be important for identifying the collected specimens.

Claims

1. A specimen collection assembly comprising:
 - an elongate specimen collection tube having an open end, a closed end and a cylindrical wall therebetween defining a tube interior for accommodating said specimen; and;
 - a cap assembly having a cap body removably sealably secured to said open end of said tube, said cap body supporting a membrane for providing therethrough pierceable probe access to said tube interior, said membrane being formed of a thermoplastic elastomer and being self-sealing upon probe removal.
2. The specimen collection assembly of Claim 1, wherein said membrane is disc-shaped having a flat surface, an opposed concave surface facing away from said tube interior and is sealingly supported by said cap body.
3. The specimen collection assembly of Claim 2, wherein said cap body comprises an upper surface, an opposed lower surface and a cylindrical side wall therebetween, said cylindrical side wall being sealably engageable with said open upper end of said tube.
4. The specimen collection assembly of Claim 3, wherein said cap body further comprises a depending annular skirt extending from said upper surface of said cap body, said cylindrical side wall and said annular skirt defining an annular region therebetween for accommodating said open end of said tube, said annular skirt defining an access passageway through said cap body and said membrane being supported within said access passageway.
5. The specimen collection assembly of Claim 4, wherein said annular skirt comprises an elongate cylindrical skirt wall having an upper end and a lower end with said passageway being defined therebetween, said lower end of said skirt wall extending into said tube interior and said membrane being sealingly supported across said lower end of said skirt wall.
6. A cap assembly for sealably covering an open ended specimen collection container comprising:
 - a cap body being formed of rigid material for removable securement over said open end of said container; and
 - a pierceable septum supported by said cap body for providing probe pierceable access to said container through said cap, said pierceable septum being formed of a thermoplastic elastomeric membrane capable of self-sealing upon probe removal.
7. The cap assembly of Claim 6, wherein said cap body defines a probe passageway therethrough, said septum is supported across said passageway and is a disc-like member having one concave surface for facilitating said self sealing.
8. The cap assembly of Claim 6, wherein said cap body comprises an upper surface, an opposed lower surface and a cylindrical sidewall therebetween.
9. The cap assembly of Claim 8, wherein said cap body further comprises a depending annular skirt extending from said upper surface of said cap body, said cylindrical sidewall and said annular skirt defining an annular region therebetween, and said annular skirt defining an access passageway through said cap body and said membrane being supported within said access passageway.
10. The cap assembly of Claim 9, wherein said annular skirt comprises an elongate cylindrical skirt wall having an upper end and a lower end with said passageway being defined therebetween, and said membrane being sealingly supported across said lower end of said skirt wall.

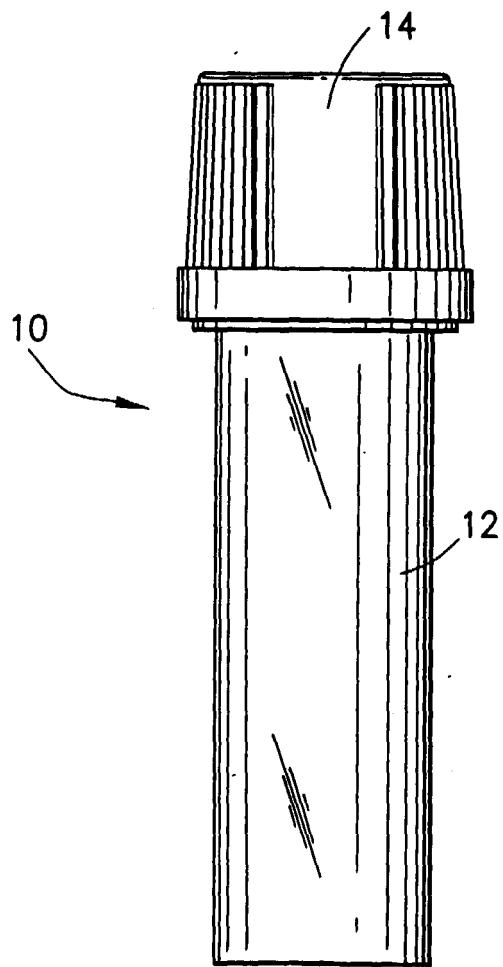


FIG.1

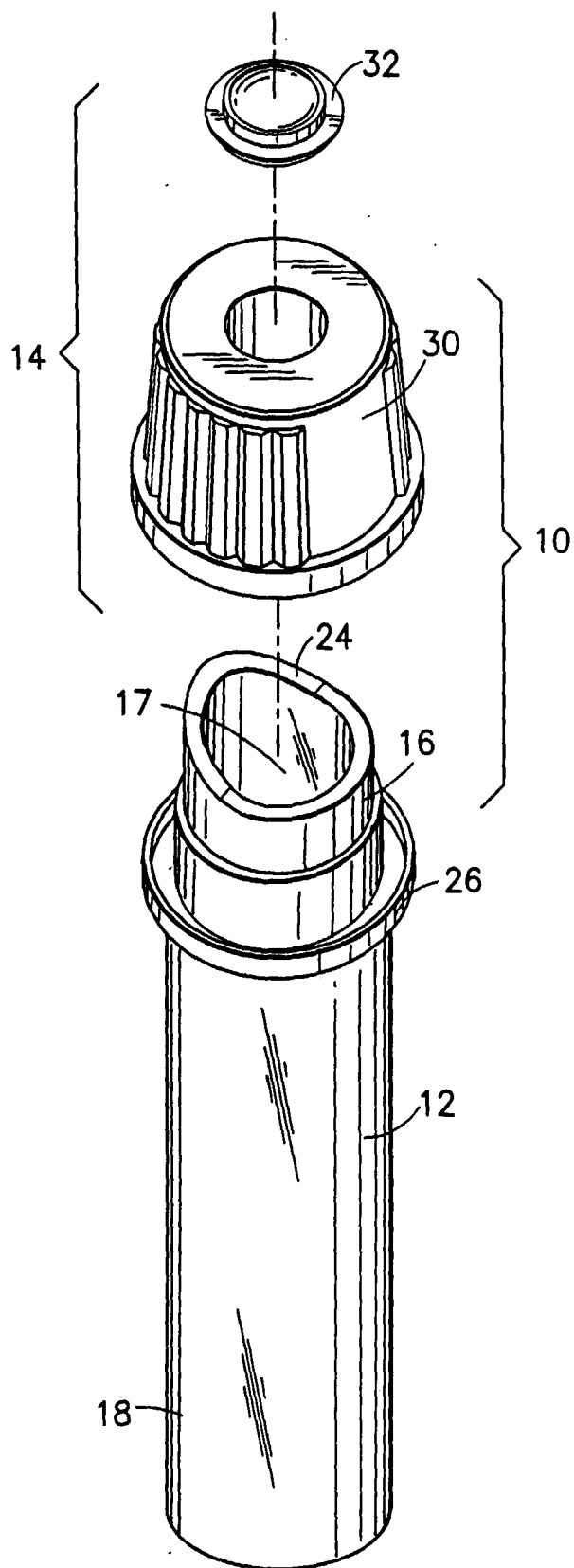


FIG.2

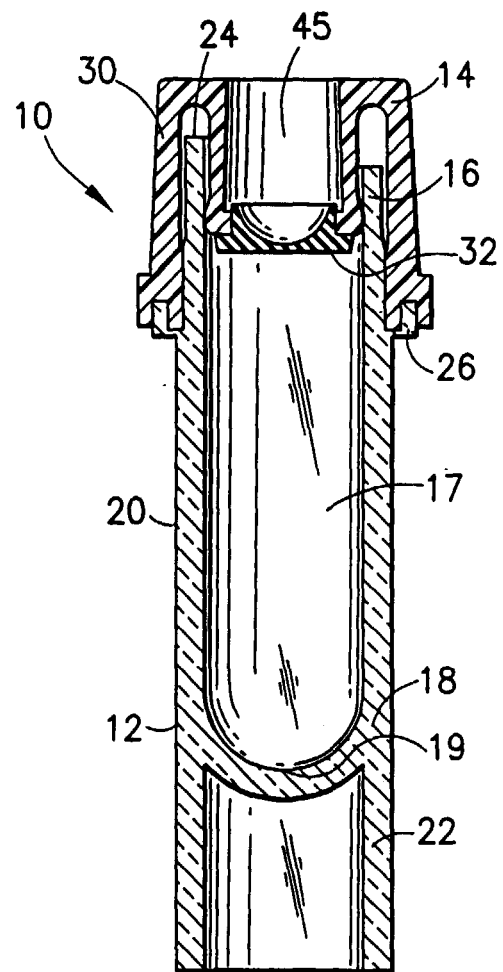


FIG.3

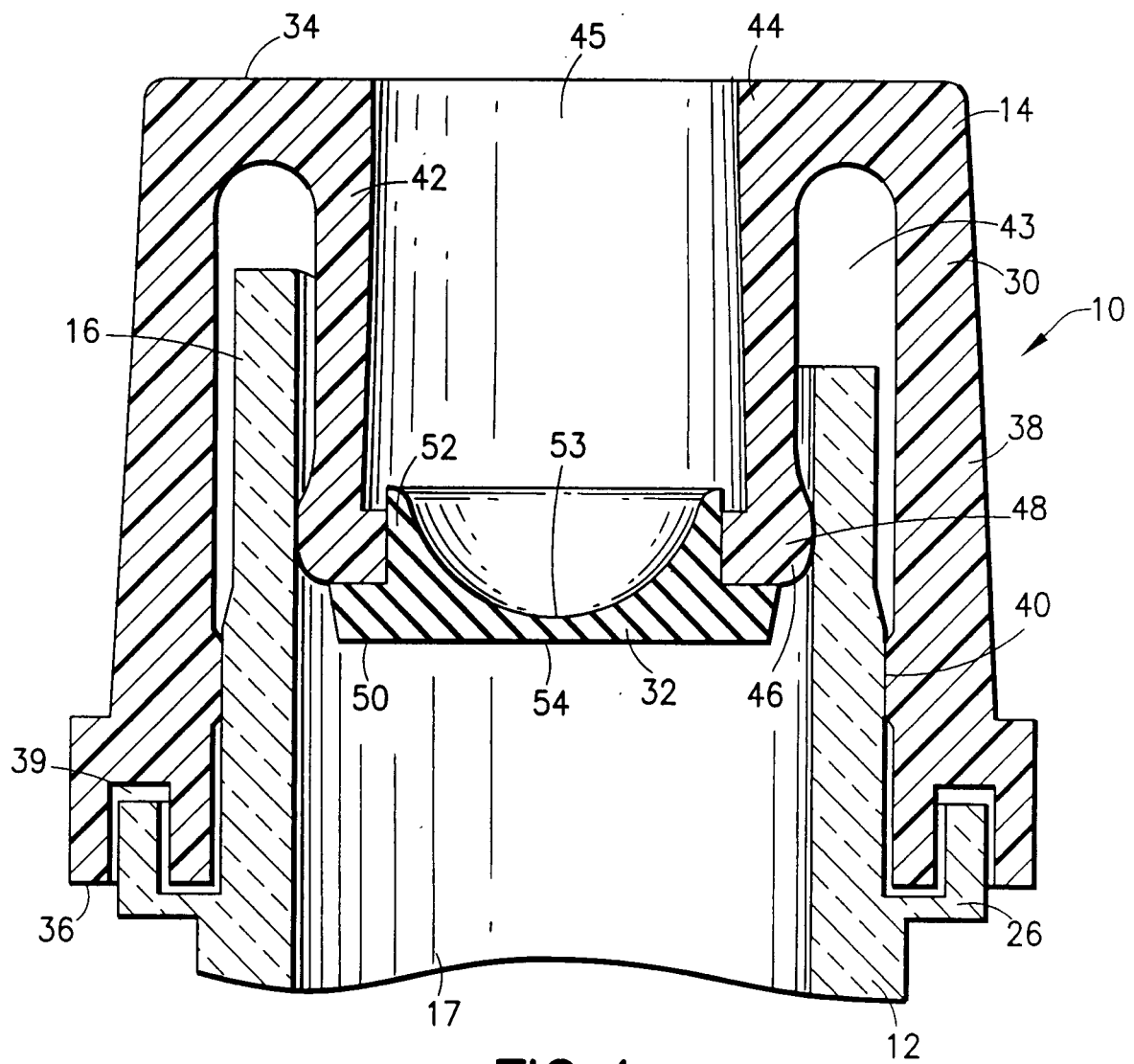


FIG.4

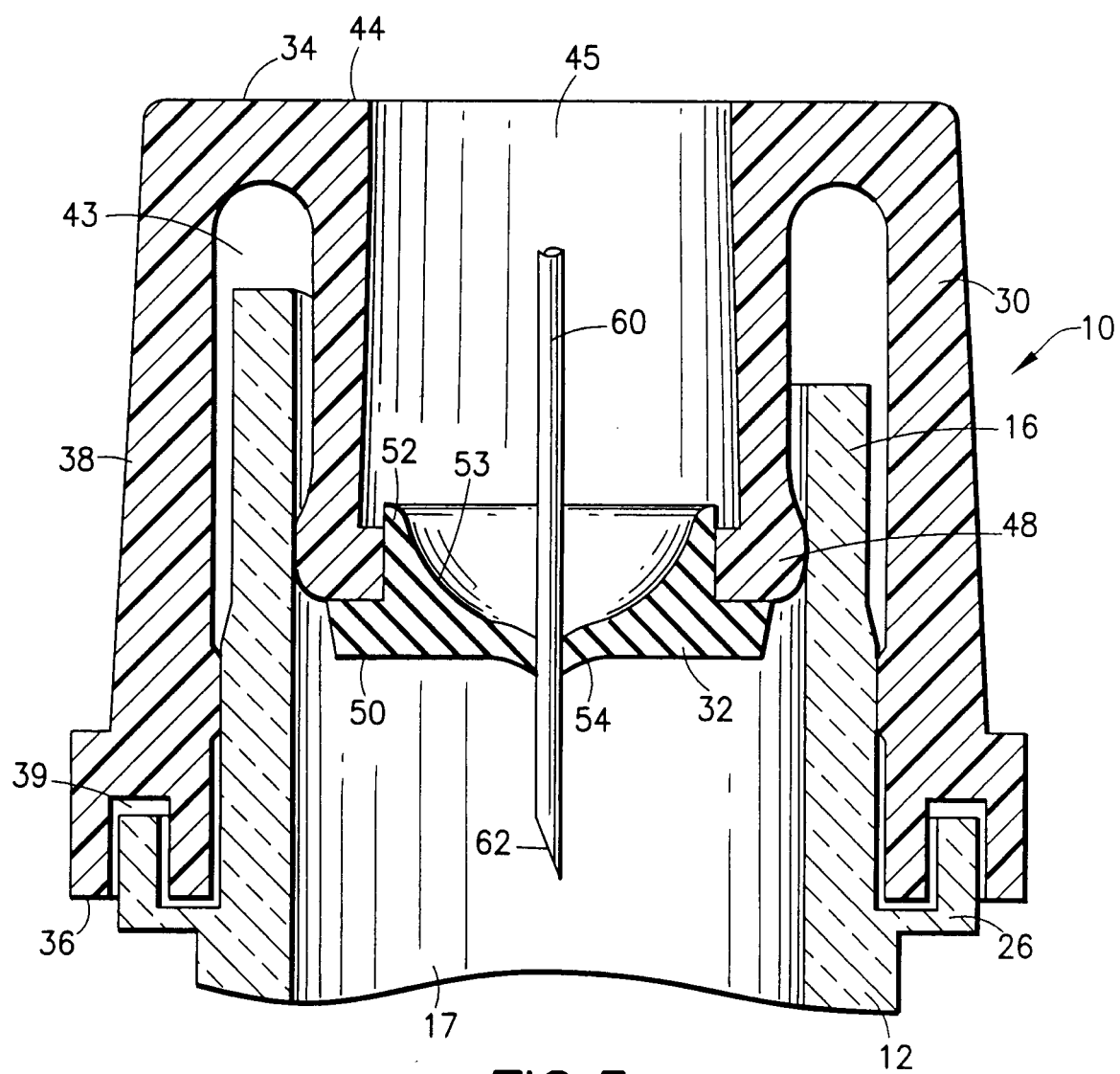


FIG.5